



ECSi

"Your Regulatory Compliance Expert"

October 28, 2021

Emily Liu
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1650 Santa Ana Avenue
Sacramento, California 95838

Subject: **RESULTS OF ETHYLENE OXIDE SOURCE TESTING PERFORMED AT THE JACKSON LABORATORY IN SACRAMENTO, CALIFORNIA**

Dear Ms. Liu:

Please find attached the results of the biennial ethylene oxide source testing and leak testing performed at your facility on Thursday, October 28, 2021, by ECSi. These test results are to be kept with all records pertaining to Sacramento Metropolitan Air Quality Management District (SMAQMD) required testing of the EtO gas-sterilization system, and are to be made available upon request by the SMAQMD. A copy of all raw test data, complete with sample chromatograms and calibration data, will be maintained in our files, and will be made available upon request.

Testing was performed in accordance with the SMAQMD and CARB requirements. The EtO concentration at the inlet and outlet of the emission-control device was measured simultaneously following the procedures delineated in CARB Method 431. During the source test, vented gas was analyzed by an SRI, Model 8610, portable gas chromatograph (GC), equipped with the following: dual, heated sample loops and injectors; dual columns; and dual detectors. A flame ionization detector (FID) was used to quantify emissions at the emission-control device inlet, and a photoionization detector (PID) was used to quantify emissions at the emission-control device outlet.

The test results show that you continue to operate your EtO sterilization and emission-control system in compliance with SMAQMD regulatory requirements, and with the requirements specified in your SMAQMD Permit. The emission-control device demonstrated an EtO control efficiency of 99.40% (the requirement is 99.0%). The entire system was also found to be leak free.

If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer
ECSi

TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE
OPERATED BY THE JACKSON LABORATORY
IN SACRAMENTO, CALIFORNIA
ON OCTOBER 28, 2021

<u>CYCLE PHASE</u>	<u>INJECTION TIME</u>	<u>INLET ETO CONC. (PPM)(1)</u>	<u>OUTLET ETO CONC. (PPM)(2)</u>	<u>ETO CONTROL EFFICIENCY</u>
Exhaust(3)	1212	2050	11.6	99.43
Exhaust	1215	1890	8.11	99.57
Exhaust	1218	1520	7.85	99.48
Exhaust	1221	1210	8.68	99.28
Exhaust	1224	1040	9.98	99.04
Exhaust	1227	1190	10.8	99.09
Exhaust	1230	1860	18.2	99.02
Exhaust	1233	1270	11.6	99.09
Exhaust	1236	709	5.54	99.22
Exhaust	1239	1660	10.5	99.37
Exhaust	1242	1010	9.14	99.10
Exhaust	1245	696	5.20	99.25
Exhaust	1248	421	2.39	99.43
Exhaust	1251	230	1.60	99.30
Exhaust	1254	180	0.64	99.64
Exhaust	1257	107	0.08	99.93
Exhaust	1300	62.8	0.01	99.98
Exhaust	1303	<u>40.3</u>	<u>0.01</u>	<u>99.98</u>
TIME-WEIGHTED AVERAGE:		952.6	6.7739	99.40
SMAQMD REQUIRED CONTROL EFFICIENCY:				99.0

Notes:

(1) - PPM = parts per million by volume

(2) - 0.01 ppm is the quantification limit for the detector used at the outlet.

(3) - The exhaust phase started at 12:05, ended at 13:05.

TABLE 2
ETHYLENE OXIDE MASS EMISSIONS
FROM A GAS STERILIZATION AND EMISSION CONTROL SYSTEM
OPERATED BY THE JACKSON LABORATORY
IN SACRAMENTO, CALIFORNIA
ON OCTOBER 28, 2021

<u>CYCLE PHASE</u>	<u>STACK FLOW(1)</u>	<u>OUTLET ETO MASS FLOW(2)</u>	<u>MINUTES/ CYCLE</u>	<u>CYCLES/ YEAR</u>	<u>ANNUAL ETO MASS EMISSIONS(3)</u>
Exhaust	49.9 DSCFM	0.00003867 lbs/min	60	260	0.6032 lbs/year
TOTAL ANNUAL ETO MASS EMISSIONS					0.6032 lbs/year

Notes:

(1) - DSCFM = Dry Standard Cubic Feet per Minute

(2) - lbs/min = pounds per minute

(3) - lbs/year = pounds per year

TABLE 3
ETHYLENE OXIDE LEAK TESTING
OF A GAS STERILIZATION SYSTEM
OPERATED BY THE JACKSON LABORATORY
IN SACRAMENTO, CALIFORNIA
ON OCTOBER 28, 2021

<u>COMPONENT GROUP TESTED</u>	<u>LEAKING COMPONENTS FOUND</u>	<u>CONCENTRATION</u>
Gas Cartridge / Injector	None	<1.0 ppm (1)
Sterilizer Inlet / Inbleed Valve	None	<1.0 ppm
Door Seal	None	<1.0 ppm
Sterilizer Outlet / Chamber Drain	None	<1.0 ppm
Venturi System / Filter	None	<1.0 ppm
Emission Control Device Inlet	None	<1.0 ppm

Notes:

(1) - PPM = parts per million by volume

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Ethylene Oxide Mass Emissions Data and Calculations

The Jackson Laboratory - Sacramento, CA - October 28, 2021

<u>DeltaP</u>	<u>SqRtDeltaP</u>	<u>Temp (F)</u>	<u>ppm EtO</u>			
Exhaust Phase				stack ID =	6	in.
				stack area =	0.196	sq. in.
				press =	30.05	in. Hg
				Tstd =	528	deg R
				Pstd =	29.92	in Hg
				Cp =	0.99	
				Kp =	85.49	
0.005	0.0707	294	11.60	Velocity =	6.71	ft/sec
0.005	0.0707	306	8.11	Flow =	49.9	dscfm
0.0075	0.0866	352	7.85			
0.0075	0.0866	386	8.68			
0.0075	0.0866	391	9.98			
0.0075	0.0866	389	10.80			
0.0075	0.0866	377	18.2			
0.0075	0.0866	373	11.6	MWeto =	44.05	
0.0075	0.0866	382	5.54	MolVol =	385.32	
0.0075	0.0866	377	10.50	ppmv/ft3 =	1000000	
0.0075	0.0866	373	9.14			
0.0075	0.0866	375	5.20	EtO Mass Flow (Exh) =	0.00003867	lbs/min
0.0075	0.0866	367	2.39			
0.0075	0.0866	351	1.60	min/cycle =	60	
0.005	0.0707	334	0.64	cycles/year =	260	
0.005	0.0707	322	0.08			
0.005	0.0707	315	0.01	Annual EtO Emissions =	0.6032	lbs/year
0.005	0.0707	311	0.01			
Average =						
0.0067	0.0813	354	6.774			
		=	814	degR		